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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/028,075 | 12/21/2001 | Nisar Asmed Khan | 2183-5223US | 1102 |

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TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

| EXAMINER | |
|---|---|
| MCKELVEY, TERRY ALAN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1636 | |

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/028,075 | KHAN ET AL. | |
| | Examiner | Art Unit | |
| | Terry A. McKelvey | 1636 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *6-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 August 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10/28, 4/12, 5/19*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of Group I, claims 1-5 in the paper filed 10/28/03 is acknowledged.

Claims 6-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the paper filed 10/28/03.

### *Specification*

The substitute specification filed 8/12/02 has been entered.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Czernilofsky et al (U.S. Patent No. 5,854,004).

Czernilofsky et al teach a process for screening a test substance for the ability of the test substance to modulate a receptor-dependent signal transduction pathway in a human or animal cell, wherein said modulation affects the adenylate cyclase signal transduction pathway initiated by a receptor coupled to the signal transduction pathway, comprising incubating test mammalian cells with the test substance (which reads on contacting the test substance with at least one cell), which cells comprise a reporter gene (expression of which is affected by a change in cAMP), and measuring the concentration of the reporter gene product in control cells and test cells (which reads on determining the presence of at least one gene product in or derived from the cell) (columns 69-70). The test substance can be natural or synthetic substances, mixtures of substances (such as vegetable extracts, fermentation liquors, etc), or in particular low molecular weight synthetic organic compounds (columns 15-16). This reads on "oligopeptide or a modification or derivative thereof" because a modification or derivative of an oligopeptide, such as a fragment of hCG, reads on any change(s) to the oligopeptide, which must be read broadly to include any other compound because any other compound can be made by modifying or being derived from oligopeptides. Additionally, the specific mixtures of substances referred

taught by the reference comprise oligopeptides because oligopeptides are a part of vegetable extracts, for example. The method taught by the reference obtains information about the capacity of the test substance to regulate the expression of the reporter gene.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35

U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Czernilofsky et al (U.S. Patent No. 5,854,004) in view of Szkudlinski et al (U.S. Patent No. 6,361,992 B1).

Czernilofsky et al teach a process for screening a test substance for the ability of the test substance to modulate a receptor-dependent signal transduction pathway in a human or animal cell, wherein said modulation affects the adenylate cyclase signal transduction pathway initiated by a receptor coupled to the signal transduction pathway, comprising incubating test mammalian cells with the test substance (which reads on contacting the test substance with at least one cell), which cells comprise a reporter gene (expression of which is affected by a change in cAMP), and measuring the concentration of the reporter gene product in control cells and test cells (which reads on determining the presence of at least one gene product in or derived from the cell) (columns 69-70). The test substance can be natural or synthetic substances, mixtures of substances (such as vegetable extracts, fermentation liquors, etc), or in particular low molecular weight synthetic organic compounds (columns 15-16). This reads on "oligopeptide or a modification or derivative thereof" because a modification or

derivative of an oligopeptide, such as a fragment of hCG, reads on any change(s) to the oligopeptide, which must be read broadly to include any other compound because any other compound can be made by modifying or being derived from oligopeptides. Additionally, the specific mixtures of substances referred taught by the reference comprise oligopeptides because oligopeptides are a part of vegetable extracts, for example. The method taught by the reference obtains information about the capacity of the test substance to regulate the expression of the reporter gene. It is taught that the assay method is a sensitive and versatile functional method of providing substances which specifically influence a signal transduction pathway in the cell in receptor-dependent manner, that it reduces the number of animals needed in clinical trials, has the advantage of being capable of being automated, and is suitable for high-throughput screening programs (column 17).

Czernilofsky et al do not specifically teach testing of fragments of hCG in their assay. This reference also does not specifically teach determining the presence of the gene product which has not been contacted with the (test substance) and determining the ratio of gene product determined in the presence of the test substance to the gene product found in the absence of the test substance.

Szkudlinski et al teach production and testing of the activity of fragments and modified fragments of glycoprotein hormones such as hCG (columns 5, 9-10, and 13-14). This reference teaches that the effect of the modification or modifications can be ascertained in any number of ways, such as by measuring cAMP production, and that one skilled in the art can readily determine any appropriate assay to employ to determine the activity of either a wild-type or modified glycoprotein hormone (column 14). Szkudlinski et al also teach assaying the increased activity of the modified glycoprotein hormone over the wild type glycoprotein hormone (indicated as n-fold, which is a ratio of the activity of the modified glycoprotein hormone to the wild type glycoprotein hormone (because it is measured in the absence of the test modified glycoprotein hormone, reads on step c) of claim 5) (column 14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the assay method taught by Czernilofsky et al to test the fragments and modified fragments of glycoprotein hormones such as hCG taught by Szkudlinski et al because Czernilofsky et al teach that it is within the ordinary skill in the art to use the assay method taught by the reference to screen any natural or synthetic test substance for the ability of the test substance to modulate a

receptor-dependent signal transduction pathway in a human or animal cell by measuring the concentration of a gene product which has its expression affected by a change of cAMP and Szkudlinski et al teach that it is within the ordinary skill in the art to test the activity of test modified glycoproteins by measuring cAMP production or any other appropriate assay.

One would have been motivated to do so for the expected benefit of applying the advantages of the assay as taught by Czernilofsky et al, such as the assay being sensitive, versatile, capable of being automated, and suitable for high-throughput screening programs, to the modified glycoprotein hormones to be tested as taught by Szkudlinski et al. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Regarding determining the ratio of the gene product in the presence versus the absence of the test substance, it would have been obvious to do so because Szkudlinski et al teach doing so.

## ***Conclusion***

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**Terry A. McKelvey, Ph.D.**
**Primary Examiner**
**Art Unit 1636**

January 24, 2004